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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,197	12/21/2001	William Canfield	209794US0	4478

22850 7590 11/25/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 10/024,197	Applicant(s) CANFIELD, WILLIAM	
	Examiner Elizabeth Slobodyansky	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-19 and 62-79 is/are pending in the application.
- 4a) Of the above claim(s) 63-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-19, 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7/23/03, 9/18/03</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed September 8, 2003 canceling claims 1-11 and 20-61, amending claim 12 and adding claims 62-79 has been entered.

Claims 12-19 and 62-79 are pending. It is agreed with Applicants that new claim 62 is drawn to the elected subjected matter while claims 63-79 are drawn to non-elected subject matter. Thus, claims 12-19 and 62 are under examination. Claims 63-79 are withdrawn.

Terminal Disclaimer

The terminal disclaimer filed on September 8, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,534,300 (Canfield) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

Claim 12, with dependent claims 13-19 and 62, is objected to because of the following informalities: Claim 12 recites "phosphodiester β -GlcNAcase" where it appears "phosphodiester α -GlcNAcase" is intended.

Furthermore, claim 12 recites abbreviations "GlcNAc" in "GlcNAc phosphotransferase" and "GlcNAcase" in "phosphodiester α -GlcNAcase". It is

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suggested that the first time an abbreviation is used in a claim, that the abbreviated term be written out in full, followed by its abbreviation in parenthesis.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-19 and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to or depend from a genus of "highly phosphorylated acid β -glucocerebrosidase" obtained by two step method comprising contacting an acid β -glucocerebrosidase (GBA) with any GlcNAc-phosphotransferase and subsequently with any phosphodiester α -GlcNAcase. Said method is known in the art (e.g., Baranski et al. (JBC, 267, 23342-23348, 1992, form PTO-1449 filed July 23, 2003, reference BZ). The genus of said highly phosphorylated acid β -glucocerebrosidases encompasses acid β -glucocerebrosidases from any source, both naturally occurring and man made,

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of any polypeptide structure having any number of various oligosaccharides, including mannose, with any percent of said oligosaccharides being bis-phosphorylated and linked to a polypeptide chain in any way. While claim 62 limits the amino acid structure of GBA to SEQ ID NO:26, the specification does not describe what type of oligosaccharides and which percent of them is bis-phosphorylated. The specification teaches in general terms the production of a phosphorylated human GBA by method comprising two steps of contacting an acid β -glucocerebrosidase with a GlcNAc-phosphotransferase and subsequently with a phosphodiester α -GlcNAcase (pages 35-36). Said GBA is highly modified with mannose 6-phosphate (M6P). However, while the specification discloses that "a highly phosphorylated GBA was obtained" (page 37, lines 4-6), there is no description of the structure of said highly phosphorylated GBA and the percent of bis-phosphorylated oligosaccharides, including mannose. Therefore, the genus of highly phosphorylated GBA comprises various amino acid structures and various carbohydrate moieties. With regard to the latter, the carbohydrate moiety of "highly phosphorylated GBA" is a genus comprising oligosaccharides of any structure and bis-phosphorylated to various degrees.

Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-19 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “ highly phosphorylated acid β -glucocerebrosidase” is defined on page 15 of the specification by non-limiting examples, rendering the metes and bounds of the claim unascertainable.

Response to Arguments

Applicant's arguments filed September 8, 2003 have been fully considered but they are not persuasive.

With regard to the 112, 1st paragraph, written description rejection, Applicant argues that “Highly phosphorylated as known in the art and described in the specification on page 15 relates to the presence of bis-phosphorylated oligosaccharides on the enzyme” (Remarks, page 7). This is not persuasive because this term includes not only bis-phosphorylated mannose residues but also other oligosaccharides and any percent of mannose residues that are bis-phosphorylated.

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With regard to the 112, 2nd paragraph, Applicant argues that "term "highly phosphorylated GBA" is defined on page 15 (page 8). This is not agreed with for the reasons stated in the rejection above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

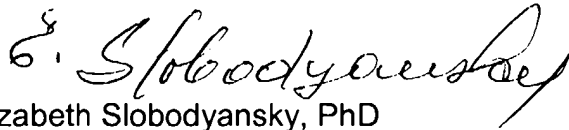
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky". The signature is written in black ink and is positioned above the printed name and title.

Elizabeth Slobodyansky, PhD
Primary Examiner

November 21, 2003